

Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers (KEEP-P)

NCT03106636

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1. STATISTICAL ANALYSIS PLAN APPROVAL SIGNATURES

Revision History

Version 1: 4/30/2020

Version 2: 6/2/2020

2. ABBREVIATIONS

DD	Developmental Disabilities
PMT	Parenting Management Training
FIND	Filming Interaction to Nurture Development
KEEP-P	Keeping Parents Supported and Trained – Preschool
KEEP-P+	Keeping Parents Supported and Trained – Preschool + FIND
EF	Executive Function

ANOVA	Analysis of variance
T1	Time 1
T2	Time 2
PSI	Parenting Stress Index
PSOC	Parenting Sense of Competency Scale
FRQ	Family Routines Questionnaire
ADRY	Parent Attachment Diary
IEMP	Interpersonal Mindfulness in Parenting
CBCL	Child Behavior Checklist
PKBS	Preschool and Kindergarten Behavior Scales
PDR	Parent Daily Report
ASQ	Ages and Stages Questionnaire
DCCS	Dimensional Change Card Sort
KRISP	Kansas Reflection-Impulsivity Scale for Preschoolers

3. INTRODUCTION

During the transition into school, children encounter a range of developmental challenges which impose significant social and cognitive demands. Emotional and behavioral self-regulation is critical to successful school adjustment. This transition may be particularly challenging for children with emerging developmental delays or disabilities (e.g., autism, intellectual disability) who experience more self-regulation difficulties and problem behaviors than typically-developing children. Early intervention is critical to minimize negative outcomes, and there is evidence to suggest that consistent, supportive parenting practices is effective for children with developmental disabilities (DD), particularly for promoting self-regulatory abilities and managing problem behaviors (Roberts, Mazzucchelli, Studman, Sanders, 2006). Given the importance of regulatory skills during the transition to school, parenting may be an early, malleable target to support school readiness and improve behavioral, emotional, and cognitive outcomes, especially for children with DD.

Parenting management training (PMT) programs have been implemented extensively with parents of typically developing children to improve behavior problems and promote positive adjustment (Kazdin, 2005). Keeping Parents Supported and Trained (KEEP) is a PMT Oregon model originally developed for supporting parents of foster children. It has been consistently effective in improving child and parent outcomes, including reduced behavior problems and associated parenting stress (Chamberlain & Reid, 1987; Chamberlain, 2002; Chamberlain, 2008; Price & Walsh, 2015; Price, Roesch, & Walsh, 2012). Filming Interactions to Nurture Development (FIND) is a video-coaching method which aims to increase the frequency of developmentally supportive interactions by showing parents instances of themselves engaging in such behaviors. It has been shown useful in enhancing child-supportive parenting which consequently reduces children's problem behaviors and improves parenting stress and competence (Fisher et al., 2016). Although PMT programs are well-validated, there is increasing interest in integrating traditional PMT models, which can focus on skill deficits, with models that emphasize and potentiate parenting strengths and capabilities.

The Keeping Parents Supported and Trained – Preschool (KEEP-P) study introduced a variation of the KEEP intervention model which included the strengths-based video-coaching methods of FIND. With participating families randomly assigned to either the KEEP-P program or the KEEP-P + FIND (KEEP-P+) program, the study was a randomized control trial that compared the efficacy of the two varied models of KEEP in children with DD. The study used a two-group (experimental and active control) mixed design that examined repeated measures, but was not factorial. Institutional review board (IRB) approval was obtained from the University of Oregon, and the trial is registered with Clinical Trials.gov (NCT03106636).

4. STUDY OBJECTIVES

Primary Objective

The primary objective of the study is to examine and compare the efficacy of a traditional KEEP parenting management training intervention (KEEP-P) with a variation of the KEEP model (KEEP-P+) on a range of both child and parent outcomes, specifically in families with children with DD. We hypothesize that the addition of the video coaching in the KEEP-P+ condition will result in significantly enhanced socioemotional functioning, executive function (EF), and longer-term educational outcomes (i.e., KEEP-P+ > KEEP-P).

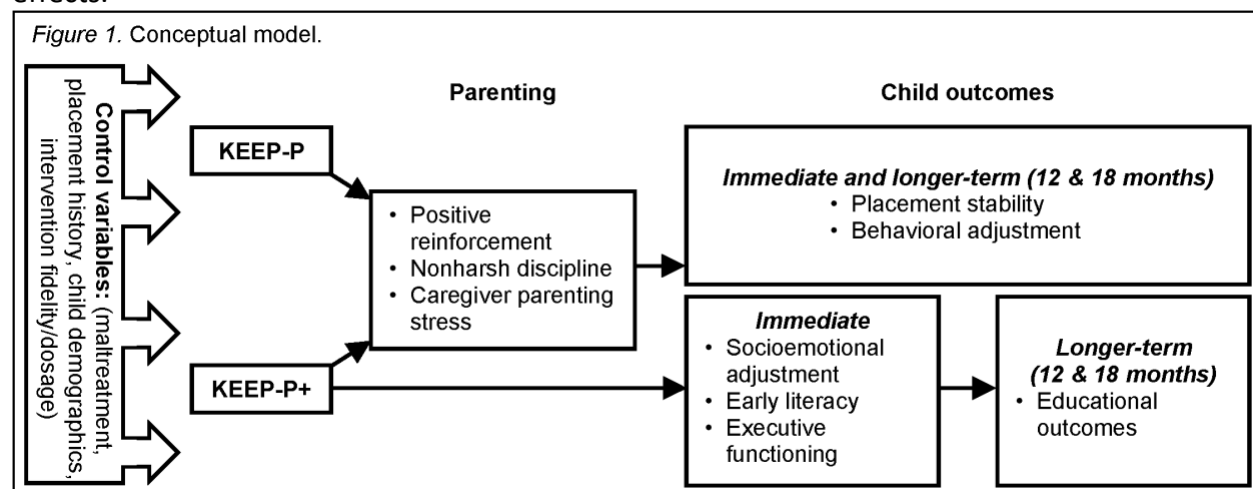
As the title describes, the project began as a study on foster preschoolers. However, due to a number of practical and logistical problems that led to low recruitment numbers, the investigative team added recruitment through early intervention/early childhood special education service providers with approval from NICHD. The EI/ECSE population has considerable overlap with the foster care population in terms of high risk for poor outcomes and negative life course trajectories. While analyzing the study's results, the investigative team found that 1) The EI/ECSE sample made up the vast majority of the total sample and 2) The effects and baseline scores differed greatly between EI/ECSE and DHS. Because of this, it was decided that the published results from this study would be of the EI/ECSE participants only.

Secondary Objective

The secondary objective of the study is to examine associations between sociodemographic covariates and change-over-time outcome variables, including the 12- and 18-month post-baseline outcomes. At the time of this report, only the pre- and post-intervention data has been analyzed.

5. STUDY DESIGN

Conceptual Model. The conceptual model for the proposed research is shown in Figure 1 (below). This model has guided our program of research involving foster preschoolers for over a decade. The foundation of the model (replicated in many of our prior experimental studies) is that parenting is a central mediating mechanism of interventions to improve child adjustment. Specifically, the parenting variables that have proven most malleable *and* most strongly associated with child outcomes include the use of positive reinforcement techniques and non-harsh discipline and reducing parent stress associated with child behavior problems. As illustrated in Figure 1, we hypothesize that KEEP-P *and* KEEP-P+ will produce significant main effects in terms of immediate and longer-term child outcomes in placement stability and behavioral adjustment. We hypothesize that these intervention effects will be mediated through targeted parenting variables. We further hypothesize that additional direct intervention effects will be observed for the KEEP-P+ children regarding socioemotional adjustment, early literacy, and EF, which will in turn mediate longer-term educational outcomes. The conceptual model also includes a number of observed child characteristics as control variables, including child demographics, and intervention dosage and fidelity as well as foster placement history from Child Welfare records, which might influence intervention effects.



Data Collection Procedures. Interviews were conducted at the University of Oregon in the Stress Neurobiology and Prevention (SNAP) assessment space. Caregivers and their children completed a 90 minutes assessment prior to the start of any intervention activities [Time 1 (T1)] and following the intervention [Time 2 (T2)]. Children completed standardized tests and various tabletop tasks, and parents completed semi-structured interviews and questionnaires. Caregivers were compensated \$50 for completing each wave of data collection. Families also received assistance with transportation and childcare costs to facilitate participation.

Caregiver and child measures. The assessment strategy used a multiagent, multimethod approach aimed at minimizing measurement bias and error. To measure immediate and longer-term child outcomes, we assessed attachment behavior, internalizing and externalizing symptoms, behavioral and socioemotional adjustment, and cognitive function. For parenting

outcomes, we measured parenting self-efficacy, parenting stress, and mindfulness in parenting. Control variables (e.g., demographics and intervention fidelity/dosage) was assessed. The measures were selected based on their psychometric properties, utility in defining the constructs of interest, and relevance to the proposed study. All measures have acceptable reliability and validity information on psychometric characteristics.

Table of Measures Included in Current Analyses.

Domain	Measures	Measure Description	Variable	Time Administered
Child and Parent Characteristics	Family demographics and characteristics	Parent-report	Basic Demographic Info	Baseline (T1)
Parenting Constructs	Parenting Stress Index (PSI) Short Form	Parent-report, 36-item, 5-point Likert scale from strongly agree to strongly disagree	Parenting stress	Baseline (T1) & Post-intervention (T2)
	Parenting Sense of Competency Scale (PSOC)	Modified version, parent-report, 17-item, 4-point Likert scale from strongly agree to strongly disagree	Parenting self-efficacy	
	Parenting Interactions with Children: Checklist of Observations Linked to Outcomes (PICCOLO)	Observational video coding measure	Developmentally-supportive parenting across four domains: affection, responsiveness, encouragement, and teaching	
	Family Routines Questionnaire (FRQ)	Modified version, parent-report, 28-item, measure both the frequency and rated importance of family routines, only scores of Frequency of Routines are calculated and included in the analysis	Frequency of family routines	
	Interpersonal Mindfulness in Parenting (IEMP)	Modified version, parent-report, 10-item, yield scores on three subscales: Awareness and Present-Centered	Mindful parenting	

		Attention, Non-Judgment, and Non-reactivity		
	Parent Attachment Diary (ADRY)	Parent-report, on child's reactions to three distressing incidents that are commonly experienced on a daily basis	Child attachment	
Child Mental Health and Behavior	Child Behavior Checklist (CBCL)	Parent-report, 100-item, 3-point Likert scale (0 = not true, 1 = somewhat/sometimes true, 3 = very/often true), generates scores on 9 psychopathology subscales	Child internalizing and externalizing symptoms	
	Preschool and Kindergarten Behavior Scales (PKBS)	Parent-report, 76-item, 4-point Likert scale (0 = never; 1 = rarely; 2 = sometimes; 3 = often)	Child behavior problems and social skills	
	Parent Daily Report (PDR)	Parent-report, 31-item, administered via telephone, parents were asked to indicate whether the listed behaviors occurred and rated the degree of stress related to the behavior using a 3-point Likert scale (0 = not at all; 1 = somewhat/a little; 2 = quite a lot)	Child behavior problems and associated parental stress occurring in the past 24 hours	Three times Baseline (T1) & Three times Post-intervention (T2)
Child Cognitive Function and Development	Ages and Stages Questionnaire (ASQ)	Parent-report, has 5 different versions for children age from 24-26 months/27-32 months/33-41 months/42-53 months/54-65 months	Child skills across five developmental areas: communication, fine motor, gross motor, problem-solving, and personal-social	Baseline (T1) & Post-intervention (T2)
	Dimensional Change Card Sort (DCCS)	Tabletop tasks measuring child executive function	Child executive function	
	Bear/Dragon Task			

	Kansas Reflection-Impulsivity Scale for Preschoolers (KRISP)			
	Delay Choice Paradigm			
	Spin the Pots			
	Silly Animal Categories			

6. TREATMENTS

KEEP-P: caregiver support groups. The KEEP-P caregiver support groups employ a manualized 12-session, weekly curriculum for foster, kinship, and biological caregivers. Curriculum topics comprise areas that have been found in previous studies to be malleable targets for change. The primary focus is on increasing the use of positive reinforcement and the consistent use of non-harsh discipline methods, such as redirection and brief timeouts. In addition, strategies for avoiding power struggles, reducing caregiver stress, and improving success at school are included. Each weekly 2 hour session is structured so that the curriculum content is integrated into group discussions, and primary concepts are illustrated via role-play. The 2-hour length is optimal to allow for the combination of curriculum content delivery and mutual support to occur. Home practice assignments are given weekly and relate to the topics covered during sessions to assist parents in implementing the behavioral procedures taught. If parents miss a group session, the material is delivered via a home visit. Home visits have been found to be an effective means of increasing the dosage of the intervention for families in such cases. Finally, the participants are telephoned weekly by the facilitator. They troubleshoot any problems the caregiver is having in implementing the assignment and collect information about behavior problems and caregiver stress in the past 24 hours via a behavior checklist: Parent Daily Report. The facilitator can then discuss these data at the next group meeting as a means for illustrating concepts and providing support. In prior research on the KEEP program for older children, as well as in our pilot testing of KEEP-P, these activities were not overly burdensome for caregivers, as indicated by the high rates of participation previously noted. The curriculum is designed to be delivered by well-trained and supervised paraprofessionals, who videotape each group meeting and receive weekly supervision to ensure that the program is delivered as intended (see section on fidelity below). Our prior research demonstrating the efficacy of the original KEEP program also employed paraprofessionals. Although others have questioned the use of paraprofessional intervention staff, we have found it to be an efficient and effective way to deliver services in this population that increases the scalability of an intervention.

KEEP-P + FIND: caregiver support groups plus video coaching component. The KEEP-P + FIND condition was called KEEP-Video for our project participants. This group completed the KEEP-P curriculum as above, with the addition of information about recent findings in early brain development and the elements of the FIND video coaching program. The FIND video coaching program was designed for parents and other caregivers of high-risk children. The program employs video of caregivers' natural interactions with their child to show ways that they are supporting children's healthy development. It is a simple and practical approach that emphasizes caregivers' strengths and capabilities. The video coaching program has been implemented in both individual and group settings. It begins with video recordings of a caregiver and child in their home or other natural setting. The film is carefully edited to show brief clips in which the caregiver is engaged in developmentally supportive interactions with the child. At a group coaching session, a Coach reviews the edited clips in detail with the caregivers. To cover the core concepts and elements, the Coach will review 5 sets of films with the caregivers, as well as videos developed at the Harvard Center on the Developing Child on the concept of "Serve and Return" and toxic stress. The KEEP-P + FIND component utilizes serve and return as the framework within which developmentally supportive interactions are identified. A serve occurs when a child initiates an interaction using words or gestures, or by focusing their attention on something or someone. The serve is returned when the caregiver notices and responds. Within this context, 5 specific elements of serve and return are emphasized, with an element introduced within the KEEP-P session, followed by a coaching session showing video clips from each member of the group. The five FIND elements are:

- Sharing the Child's Focus: This occurs when the adult identifies or notices what the child is interested in and then puts his/her attention there as well.
- Supporting and Encouraging: Having noticed the child's focus of attention, the adult responds in a supportive and/or positive way, adding his or her own reaction by giving the child further information about or acknowledging what he/she is seeing, doing, or feeling.
- Naming: An extension of the Supporting and Encouraging element, Naming occurs when the caregiver uses words to label what the child is seeing, doing, or feeling.
- Back & Forth Interaction: After the child has "served" and the caregiver noticed and returned the serve by Supporting and Encouraging or Naming, the interaction continues. The interaction goes back and forth between child and adult, with the adult waiting for the child's further initiations.
- Endings and Beginnings: This occurs when a Back and Forth interaction between child and caregiver ends and a new serve and return interaction begins. The end of the back and forth interaction is signaled by the child or the episode naturally comes to its conclusion (e.g., the book is finished).

Both the KEEP-P and KEEP-P + FIND curriculums are designed to be delivered by well-trained and supervised paraprofessionals, who videotape each group meeting and receive weekly supervision to ensure that the program is delivered as intended. Our prior research demonstrating the efficacy of the original KEEP program also employed paraprofessionals. Although others have questioned the use of paraprofessional intervention staff, we have found it to be an efficient and effective way to deliver services in this population that increases the scalability of an intervention.

Fidelity Monitoring and Dosage. All caregiver groups are videotaped and coded for fidelity. Caregiver group fidelity were measured using the Facilitator Adherence Ratings. This 14-item rating scale measures adherence to fidelity on three domains: content (e.g., “caregivers were encouraged to/or used a behavioral management system”), process (e.g., “The facilitator did not make critical or corrective comments”), and structure (e.g., “Facilitator managed meeting time well”). Research assistants, who were trained in the intervention model and did not participate in the delivery of the intervention, completed the ratings evaluating adherence on a 5-point scale (1 [*not at all*] to 5 [*very much*]), resulting in a summary score for each domain. We also assessed dosage via measures of participation in intervention activities. We tracked session attendance and recorded when missed sessions are delivered via home visit. Fidelity and dosage measures were included in analyses of intervention effectiveness.

7. SAMPLE SIZE JUSTIFICATION

To investigate the extent to which outcome measures of interest changed over time (one of the primary objectives of the study) we will use repeated measures ANOVAS with time and time*condition (KEEP-P vs. KEEP-P+).

To justify the sample size of the present study, we ran an F-test: Repeated Measures, within-between interaction for ANOVA using G*Power to compute power and sample size. Time is the within-subjects variable, and the intervention condition (KEEP-P vs. KEEP-P+) is the between-subjects variable. Partial eta squared is the effect size measure for the interaction between the within- and between-subjects variables. We assume a medium effect size here which means partial eta squared = .06, alpha error probability = 0.05, power = 95%, number of groups = 2, number of measurements = 2, total sample size = 54.

There is a 95% chance of correctly rejecting the null hypothesis of no significant effect of the interaction with 27 families in the KEEP-P condition and 27 families in the KEEP-P+ condition for a total of 54 families. Therefore, our sample size of n=175 provides more than enough power to conduct the analyses.

8. DEFINITION OF ANALYSIS POPULATIONS

Analysis Sets/Populations/Subgroups

175 caregivers with children were recruited through Early Childhood CARES, an EI/ECSE provider in Lane County, Oregon, and randomly assigned to KEEP-P (n = 87) or KEEP-V (n = 88). To be eligible for study participation, the child had to be identified as being at risk or with a documented developmental disability.

9. STATISTICAL METHODOLOGY

General

All data will be summarized by intervention group. For continuous variables, sample maximum, minimum, median, mean, and standard deviation will be reported. For categorical variables, counts and percentages will be reported. A significance level of 0.05 is applied for all hypothesis tests.

Handling of Missing Values and Other Data Conventions

Missing data strategies.

Our research team used several strategies to minimize missing data. During collection, the research team took great care to format the surveys and tasks in a clean and straight-forward way. If missing data was found shortly after the visit and the information could be clarified or collected, (e.g. missing item on a survey) research team members called the caregiver to ask for the information. In order to maximize our power to detect effects in scale measures, we interpolated cases with at least 80% of data available in a given subscale or total score to create a useable score.

Statistical Tests

All families who attended at least one group were included in analyses. We first investigated the extent to which outcome measures of interest changed over time using repeated measures ANOVAS with time and time*condition (KEEP-P vs. KEEP-P+) conditions. For outcomes with either time or time*condition effects, we conducted follow-up analyses investigating the influence of condition and intervention dosage (i.e., % of groups attended).

Covariates investigated included caregiver level (i.e. caregiver education, family income) and child level (i.e. child age, child gender) variables. Chi-square tests (child gender) and independent sample t-tests (caregiver education, family income, child age) were run to determine the presence of group differences at baseline. The presence of either significant group differences or associations between a covariate and change-over-time resulted in the covariate being included in all subsequent analyses.

One-way ANOVAs were then conducted between condition and covariate measures on change scores of outcome measures for outcome constructs that were of primary interest to the theory of change and that evidenced change over time, we also conducted exploratory subscale analyses (i.e., Parent Stress, Child Mental Health and Behavior, Child Development). This analytic approach was taken to demonstrate transparency of results across all measures collected.

Linear regressions were conducted to examine predictors of change-over-time in all 12 variables established to change in the main analysis. Variables included as predictors included child age, child sex, group assignment (KEEP-P or KEEP-P+), and intervention dosage (% groups attended).

10. INTERIM ANALYSES

There is no planned interim analysis for this study.

11. DATA PRESENTATION

Tables

Table 1. Means of study variables

Variable	KEEP-P Pre	KEEP-P Post	KEEP-P Change	KEEP- P+ Pre	KEEP- P+ Post	KEEP- P+ Change	All Pre	All Post	All Change
Parenting Constructs									
Parent Stress Index	80.87 (20.28)	74.62 (20.29)	-5.29 (9.45)	86.18 (23.83)	80.80 (22.76)	-5.72 (13.97)	83.55 (22.23)	77.98 (21.80)	-5.53 (12.07)
Parenting Sense of Competence	49.42 (5.18)	51.60 (5.46)	2.14 (3.39)	49.82 (6.33)	50.15 (5.22)	.30 (4.84)	49.62 (5.78)	50.82 (5.36)	1.15 (4.32)
PICCOLO	42.58 (7.22)	42.85 (8.45)	.14 (8.67)	43.36 (6.65)	43.08 (7.65)	-.76 (8.57)	42.98 (6.92)	42.97 (8.02)	-.34 (8.59)
Family Routines	51.66 (11.66)	52.63 (9.79)	1.37 (10.34)	50.43 (9.00)	52.09 (9.32)	1.30 (6.62)	51.05 (10.41)	52.34 (9.51)	1.33 (8.53)
IEMP	37.87 (3.33)	38.80 (3.36)	.81 (2.67)	37.17 (4.55)	37.56 (4.00)	.69 (4.03)	37.52 (4.00)	38.12 (3.76)	.74 (3.47)
ADRY Proximity Behavior	7.53 (3.89)	7.75 (3.83)	.22 (3.41)	8.42 (3.73)	7.87 (3.78)	-.49 (4.17)	7.98 (3.82)	7.81 (3.79)	-.16 (3.84)
ADRY Avoidant Behavior	1.84 (2.22)	1.78 (2.33)	-.03 (2.15)	1.95 (2.19)	2.06 (2.53)	-.04 (2.22)	1.90 (2.20)	1.93 (2.43)	-.04 (2.18)
ADRY Resistant Behavior	.72 (1.03)	.57 (1.08)	-.08 (.95)	.88 (1.15)	.70 (.99)	-.21 (1.10)	.80 (1.09)	.64 (1.03)	-.15 (1.03)
Child Behavior and Development									
CBCL total	59.60 (12.13)	57.18 (12.44)	-3.24 (6.95)	61.65 (11.72)	57.47 (12.14)	-3.76 (6.63)	60.61 (11.94)	57.33 (12.24)	-3.52 (6.76)
CBCL internalizing	56.62 (11.64)	55.29 (12.07)	-1.90 (7.04)	58.67 (10.22)	54.84 (11.05)	-3.17 (7.03)	57.64 (10.98)	55.05 (11.50)	-2.58 (7.04)
CBCL externalizing	58.84 (11.75)	55.87 (11.93)	-3.11 (7.42)	60.64 (12.98)	57.27 (12.48)	-3.41 (7.89)	59.73 (12.37)	56.61 (12.20)	-3.27 (7.64)
PDR stressful	6.56 (5.65)	4.48 (4.81)	-1.90 (4.59)	7.26 (5.36)	4.58 (4.11)	-2.80 (3.98)	6.91 (5.50)	4.53 (4.44)	-2.38 (4.29)
PKBS total problems	55.86 (19.56)	50.60 (21.93)	-3.44 (10.80)	54.63 (19.70)	52.39 (18.30)	-3.09 (11.02)	55.24 (19.58)	51.56 (20.00)	-3.25 (10.88)
ASQ total	121.35 (77.58)	105.00 (74.47)	-14.33 (33.95)	125.81 (66.21)	119.13 (71.29)	-2.39 (42.64)	123.60 (71.91)	112.56 (72.84)	-7.95 (39.15)
Child Cognitive Function									
Delay Choice Paradigm	4.86 (3.11)	5.24 (3.26)	.19 (3.13)	5.55 (2.91)	4.54 (3.50)	-.89 (3.41)	5.21 (3.02)	4.88 (3.39)	-.37 (3.31)
Attention Shifting DCCS	1.76 (1.43)	2.12 (1.54)	.48 (1.29)	1.61 (1.32)	2.05 (1.54)	.43 (1.37)	1.68 (1.37)	2.08 (1.53)	.45 (1.33)
Bear Dragon	21.52 (7.58)	23.60 (6.81)	1.56 (6.41)	20.42 (8.25)	22.42 (7.37)	3.24 (8.50)	20.96 (7.91)	22.97 (7.11)	2.47 (7.63)
Spin the Pots	.58 (.16)	.62 (.20)	.05 (.22)	.55 (.16)	.59 (.18)	.06 (.23)	.57 (.16)	.61 (.19)	.06 (.22)
Silly Animal Categories	.64 (.38)	.67 (.35)	.05 (.33)	.61 (.34)	.71 (.31)	.10 (.31)	.63 (.36)	.69 (.33)	.07 (.32)
KRISP	35.76 (7.90)	37.81 (6.23)	2.16 (8.97)	33.52 (7.78)	35.80 (7.60)	3.96 (7.55)	34.65 (7.89)	36.79 (7.00)	3.11 (8.26)

Table 2. Primary Outcomes Change Over Time

Primary Outcomes	<i>df</i>	Time (<i>F</i>)	Time X Group (<i>F</i>)	Group (<i>F</i>)
Key Parenting Measures				
Parent Stress Index	(1,125)	26.81***	.093	3.00
Parenting Sense of Competence	(1,122)	10.20**	5.82*	.43
Family Routines	(1,124)	2.32	.18	.98
ADRY Proximity Behavior	(1,125)	.15	1.07	.23
ADRY Avoidant Behavior	(1,125)	.04	.00	.00
ADRY Resistant Behavior	(1,125)	2.50	.43	.43
PICCOLO	(1,117)	.09	.53	.45
IEMP	(1,126)	5.29*	.07	3.49
Child Mental Health & Behavior				
CBCL internalizing	(1,130)	17.10***	1.07	.01
CBCL externalizing	(1,124)	23.79***	.05	.56
PDR total	(1,130)	40.67***	1.32	.34
PKBS total problems	(1,121)	10.91**	.03	.95
Child Cognitive Function and Development				
ASQ total	(1,127)	5.95*	3.03	.51
DCCS Attention Shift	(1,117)	13.86***	.05	.04
Bear-Dragon Total	(1,92)	9.23**	1.13	1.74
Delay Choice Paradigm	(1,106)	1.23	2.95	.72
Spin the pots	(1,114)	3.02	.55	2.89
KRISP	(1,87)	13.02***	.121	2.75
Silly Animal Cat.	(1,106)	5.80*	.56	.41

* $p < .05$; ** $p < .01$; *** $p < .001$

Table 3.

	<i>df</i>	Child Age	Child Gender	Group	Dosage
Parenting Constructs					
Parent Stress Index	(1,119)	.00	.15	.04	.04
Parenting Sense of Competence	(1,116)	.01	.39	6.25*	1.54
IEMP	(1,120)	.98	1.31	.00	.25
Child Mental Health & Behavior					
CBCL internalizing	(1,124)	.05	1.51	1.27	3.07
CBCL externalizing	(1,124)	.95	1.15	.12	.16
PDR total	(1,125)	.24	7.84**	.25	5.62*

PKBS total problems	(1,116)	2.84	1.49	.01	1.88
Child Cognitive Function & Development					
ASQ total	(1,121)	2.45	1.33	2.57	.30
DCCS Attention Shift	(1,111)	3.90	.09	.01	.43
Bear-Dragon Total	(1,86)	3.70	.01	.72	6.07*
KRISP	(1,87)	.93	.28	1.02	.70
Silly Animal Cat.	(1,106)	.11	.02	.58	.58

12. Data & Results

Sociodemographic descriptives

Caregivers were predominantly female (n = 151, 91.0%), versus male (n = 15, 9.0%) at an average age of 33.58 years (SD = 7.07; range 20 - 63) years. Nearly all caregivers reported being a child's biological parent (161, 97.0%) with other caregivers being foster or adoptive parents (5, 3.0%).

The sample primarily included children and caregivers of Euro-American/Caucasian/White race/ethnicity (n = 135, 77.1% children and n = 121, 69.1% caregivers). The next most commonly reported race/ethnic category Mixed Race/Ethnicity, (n = 17, 9.2% children, n = 34, 16.9% caregivers) and all other race/ethnic categories represented < 10% of the sample.

Primary caregiver education was coded on a continuous 14-point scale with responses ranging from 4: partial high school to 14: graduate degree. The median education level was a partial 4-year college degree (at least 1 year).

Gross annual household income was asked on a continuous 12-point scale, with response ranging from less than \$4,999 to more than 100,000. The median annual household income was \$30,000 -39,000. All families reported receiving social assistance.

Participating children were predominantly male (n = 124, 74.7%) with an average age of 47.70 months (SD = 10.48, range 28 – 70 months). The majority of caregivers reported being the child's biological parent (n = 161, 97.0%) with other caregivers being foster or adoptive parents (n = 5, 3.0%).

Attendance

Out of the 175 families, 153 attended at least one session. This included of 86.2% KEEP-P (n = 75) and 88.6% KEEP-V (n = 78), with no significant differences between groups [$\chi^2(1,175) = .24$, $p = .63$]. Average group attendance was 77.8%. 20.3% of families completed 8-49% of sessions; 17.0% of families completed 50-89% of sessions and 62.7% of families completed 90-100% of sessions.

Change over time

Repeated measures ANOVAS of collected data generally indicated a main effect of intervention, such that improvements in parent, child, and family function were observed over time for those assigned to the KEEP intervention. However minimal differences between KEEP-P and KEEP-V groups were observed. (See Table 1 for all means and Table 2 for inferential statistics).

In the Parenting domain, scores on the parent stress index decreased over time [$F(1,125) = 26.81, p < .001$] and scores on the parenting sense of competence [$F(1,122) = 10.21, p < .01$] and IEMP [$F(1,126) = 5.29, p < .05$] both increased over time. On the parenting sense of competence, there was also a significant Time*Group effect ($F(1,122) = 5.82, p < .05$) such that parents in the KEEP-P group reported greater gains over time than parents in the KEEP-V group. There were no observed changes in either the ADRY or the PICCOLO observation scales.

In the Child Mental Health and Behavior domain, parent-reported scores on all domains of child function significantly improved including the CBCL internalizing scale, CBCL externalizing scale, PDR, and PKBS (stats?). No Time*Group effects were observed.

In the Child Cognitive Function and Development domain, children exhibited fewer development problems, as measured on the Ages and Stages Questionnaire and improved executive function on 4 of 6 measures. In particular, children exhibited better performance on the DCCS, Bear-Dragon Task, KRISP, and Silly Animal Categories Tasks, with no change on the Delay Choice Paradigm or Spin the Pots measures.

Multivariate analyses

Covariate analyses indicated minimal sociodemographic covariates between groups, with the exception of child age [$t(113) = 2.19, p = .03$]. Children were older in the Keep-P group [$M(SD) = 48.87 (10.96)$ months] compared to the Keep-V group [$M(SD) = 44.63 (9.77)$ months]. For all other variables of interest including child gender, caregiver education, and household income, there were no significant differences between groups ($p > .05$).

Analyses examining associations between sociodemographic covariates and change-over-time outcome variables indicated that child sex was associated with PDR Mean Stressful Behaviors change-over-time ($t(103) = 2.89, p = .005$) with female children more likely to exhibit reduced stressful behaviors over time [$M(SD)$: females – 4.92 (5.07) ; males -2.03 (3.91)]. Child age was associated with PICCOLO change scores in that older children were more likely to have parents with declining PICCOLO scores over time ($r = -.20, p = .045$). There were no other associations between sociodemographic covariates of interest and any outcome variables (for full list, see Table 1). Based on these analyses, child age and sex were included as covariates in subsequent analyses.

Linear regressions were conducted to examine predictors of change-over-time in all 12 variables established to change in the repeated measures ANOVAS. Variables included as predictors included child age, child sex, group assignment (KEEP-P or KEEP-V), and intervention dosage (% groups attended). Results are presented in Table 3. Across the 12 regression analyses, higher intervention dosage predictor a greater reduction in PDR of child stressful behaviors and greater improvements in child performance on the Bear Dragon Task. Consistent with reported covariate analyses, female children were also more likely to exhibit a greater reduction in PDR of child stressful behaviors. Consistent with the reported repeated measures ANOVAS, group was a significant predictor of change in Parenting Sense of Competency over time, with parents in the KEEP-P group reporting greater gains relative to

those in the control condition. Group was not a predictor in change over time for any other variable.

13. Institutional Review Board (IRB) Protocol Documents

IRB protocol amendment forms are included in the pages that follow.

14. Informed Consent Forms

Informed Consent Forms are included in the pages that follow.



DATE: January 28, 2015

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

Notice of IRB Review and Approval – Amendment
Full Board Review as per Title 45 CFR Part 46

The amendment submitted on December 18, 2014 to the above identified project has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services. The amendment was reviewed by the fully convened IRB in accordance with HHS regulations requiring the IRB to employ additional criteria when reviewing research that does not qualify for an expedited review. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

Amendment:

- Research Plan: Minor changes are proposed for clarification or to complete information that was in draft form at the time of initial IRB submission.
 - KEEP-P: Caregiver support groups. The description of the support groups being 90 minutes was inaccurate and should have read 2 hours.
 - Intervention Manuals. Draft versions of the KEEP-P and KEEP-P+ intervention manuals were included with the initial IRB submission. These manuals have since been finalized, as is now noted in the research plan.
- Informed Consent Documents: Requested some small changes, corrections and additions to the consents for clarity and to provide additional information to participants.
 - Changes to Interview Visit Chart in Consent forms for Caseworker and Caregiver (Foster)
 - The Foster Child was removed from the interview chart at the 3rd and 4th visits.
 - Corrections to Caregiver Statement of Informed Consent. What will we ask you to do if you choose to be in the project? Correct text to read that the parent and child will complete two assessments together and the parent will complete two without the child.



- Address info added for the parent group held at Oregon Community Program (OCP) located at 1170 Pearl St, Eugene, OR 97401.
- Corrections to Caseworker Statement of Informed Consent: What is the purpose of the project? Corrected the total post-test visits the child participates in from three post-test visits to one post-test visit.
- Address info added: As above. Requesting the addition of the address for the parent group held at Oregon Community Programs (OCP) located at 1170 Pearl St, Eugene, OR 97401.
- What will we ask the child to do if she/he joins the project: Corrected the information to read that they will ask the child to complete two interviews over the next 18 months.
- How long is the project? Updated the information to be consistent throughout the caseworker consent. The child will be in the project for 6 months and data will be collected about the child for 18 months.
- Addition of Parent Informed Consent (Bio/Adoptive): As we anticipate that participating children will be reunified with their biological families or placed with adoptive families, we have added Parent consent documents.
- Requesting the addition of the interview instrument All My Children Family Summary (AMC, attached)
- Service Utilization Interview (SERV, attached) was updated with newer.
- Caregiver Demographics Questionnaire (DEMO, attached) has been shortened and where necessary language has been updated.
- Shortened the Early Learning Interview (ELINT, attached) and are only administering section D - Emerging Literacy and Numeracy.
- Removed the Caregiver Interview (CARINT), Peabody Picture Vocabulary Test IV and Vineland Adaptive Behavior Scales II questionnaires.
- Submitted a copy of the Interaction Task script (attached).
- Changes to KEEP-P CG Group Info Letter: Corrected this caregiver information sheet for the KEEP-P and KEEP-P+ conditions by removing mention of the Parent Daily Report (PDR) calls. The PDR calls are completed by the research team.
- Addition of Teleform and Qualtrics options for completing the interview and questionnaires via Teleform versions or via computer using Qualtrics.
- Addition of Assessor/Interviewer Impressions for Child and Caregiver/Parent Assessments.
- Addition of Parent Group Fidelity (PARFID, attached):
- Changes to Caregiver/Parent Phone Script
- Changes to Caseworker Email Text and Attachment
- Addition of Caregiver KEEP-P Introduction Letter and Flyer:



- Corrections/Updates to the KEEP-P Measures Table
- The Wechsler Preschool and Primary Scale of Intelligence (WPPSI) was inadvertently included as a post-intervention measure in the KEEP-P measures table. This was an error; the WPPSI will only be administered at baseline. The corrected document is attached.
- The approved protocol includes the Delay Choice Paradigm and the Delay of Gratification, which were inadvertently left off of the measures table. This has been corrected.
- Additions to research team staff:
 - Alexander Wagnon, Bryna Cooper, Alexander Heinz, Lisa Shimomaeda, Madeline Cresswell

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however the assent process described in the protocol should still be utilized.

This approval is given with the following standard conditions:

- You are approved to conduct this research only during the period of approval cited below;
- You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
- You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
- You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
- You will only use the approved informed consent document(s) (enclosed);
- You will give each research subject a copy of the informed consent document;
- If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on January 13, 2016.

Important Note: Any research personnel that have not completed CITI education certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI education certificate.



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Approval Period: January 28, 2015 - January 13, 2016

The Committee has determined all future continuing reviews are to be conducted via Full Board review procedures.

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Kalindi Allen
Research Compliance Administrator

CC: Sarah Haffner
Kristen Greenley



DATE: July 16, 2015

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of IRB Review and Approval – Amendment
Full Board Review as per Title 45 CFR Part 46**

The amendment submitted on April 27, 2015 to the above identified project has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services. The amendment was reviewed by the fully convened IRB in accordance with HHS regulations requiring the IRB to employ additional criteria when reviewing research that does not qualify for an expedited review. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however the assent process described in the protocol should still be utilized.

Amendment – the amendment request included the following:

- Research Plan changes include
 - Updated to include a community-based sample of other high-risk children. The community sample will include parents involved in early intervention/early childhood special education services and referred to KEEP-P as part of a partnership with Early Childhood CARES (EC CARES).
 - Updated recruitment plan to offer intervention services to all caregivers. Mention of a services as usual (SAU) research group has been removed.
 - Revised the parent group curriculum from 16 weeks long to 12 weeks. This change is less burdensome for families attending the Parent Groups.
 - Sample numbers have been adjusted for the groups but our total sample size will remain about the same, up to 240.
 - Added the option of completing the follow-up assessments by phone.
 - Removed Co-Investigator Cynthia Healey who is no longer involved in the project.

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- Added EC CARES locations to the section Data Collection Procedures.
- Updated Staff: Melanie Berry and Madeline Creswell
- Previously Approved Informed Consent Documents - small changes, corrections and additions to the current consents for clarity, continuity and to provide additional information to participants as well as update the procedures for the changes noted above in the Research Plan.
- Community Informed Consent - created a new consent document for the community sample.
- Measures were updated as follows
 - All Caregivers/Parents - two measures (Behavior Management Questionnaire (BMQ) and our Caregiver Demographic Questionnaire (DEMO)) updated the word “foster” from in front of parent to facilitate administration to the community sample.
 - Community Sample Only – added two measures to be completed by the community sample in order to allow for comparison with the child welfare sample including the Adverse Childhood Experiences Survey (Adult Version) and Childhood Experiences Survey (Child Version).
- KEEP-P Measures Table – was updated to reflect the above noted changes/additions to measures.

This approval is given with the following standard conditions:

- You are approved to conduct this research only during the period of approval cited below;
- You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
- You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
- You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
- You will only use the approved informed consent document(s) (enclosed);
- You will give each research subject a copy of the informed consent document;
- **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on January 13, 2016.**

Important Note: *Any research personnel that have not completed CITI education certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI education certificate.*

Approval Period: July 16, 2015 - January 13, 2016

The Committee has determined all future continuing reviews are to be conducted via **full board** review procedures.



UNIVERSITY OF OREGON

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Caitlin Alcorn, CIP
Research Compliance Administrator

CC: Sarah Haffner and Kristen Greenley, Project Coordinators

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DATE: January 20, 2016

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive
Intervention for Foster Preschoolers"

Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46
Expedited Categories # 5, 6, 7

The amendment submitted on December 14, 2015 for the project identified above has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

Amendment: This amendment updates research personnel to clarify roles, add personnel, and remove those no longer engaged in related human subject research activities. Additionally, the Personnel Form for this protocol is formally established with this amendment.

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;

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5. You will only use the approved informed consent document(s) (enclosed);
6. You will give each research subject a copy of the informed consent document;
7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on December 15, 2016.**

***Additional Conditions:** Any research personnel that have not completed CITI certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI certificates.*

Approval period: January 20, 2016 - December 15, 2016

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Caitlin Alcorn, CIP
Research Compliance Administrator



DATE: April 28, 2016

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 #5, 6, 7**

The amendment submitted on April 19, 2016 for the project identified above has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

Amendments:

- Added Kaitlyn Franklin, Sevag Makasdjian, Adrian Lopez, and Cassandra Acosta to the protocol as research assistants
- Added a participant re-contact form
- Updated question #15 of the Demographic interview
- Updated the KEEP-screener
- Added the option of texting to contact participants

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;

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5. You will only use the approved informed consent document(s) (enclosed);
6. You will give each research subject a copy of the informed consent document;
7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on December 15, 2016.**

***Additional Conditions:** Any research personnel that have not completed CITI certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI certificates.*

Approval period: April 28, 2016 - December 15, 2016

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Daniel Berman
Research Compliance Administrator

CC: Sarah Beecroft-Haffner, Project Coordinator
Kristen Greenley, Project Coordinator



DATE: July 18, 2016

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive
Intervention for Foster Preschoolers"

Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46
Expedited Categories # 5, 6, 7

The amendment submitted on May 31, 2016 for the project identified above has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

Amendment: Update screening form as well as update personnel.

*Note- Two versions of the screening form were submitted and reviewed because the formatted pdf version was hard to update so a word version was created and submitted for these submissions and it is assumed the pdf version is then updated once the content is finalized. Two different screening forms are not used.

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;



4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
5. You will only use the approved informed consent document(s) (enclosed);
6. You will give each research subject a copy of the informed consent document;
7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on December 15, 2016.**

Additional Conditions: *Any research personnel that have not completed CITI certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI certificates.*

Approval period: July 18, 2016 - December 15, 2016

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Kalindi Allen
Research Compliance Administrator



DATE: October 03, 2016

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # 5, 6, 7**

The amendment submitted on September 26, 2016 for the project identified above has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

The purpose of this Amendment is to:

- Update research personnel to include Jenette Arellano, Jessie Moyer, and Danielle Schaer and remove Catherine Hamby, Sevag Makasdjian, and Aundrea Braniff.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
5. You will only use the approved informed consent document(s) (enclosed);
6. You will give each research subject a copy of the informed consent document;



7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval the Protocol will automatically expire on December 15, 2016.**

Additional Conditions: Any research personnel that have not completed CITI certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI certificates.

Approval period: October 03, 2016 - December 15, 2016

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Lizzy Utterback
Research Compliance Administrator

CC: Kristen Greenley, Project Coordinator
Alexander Wagnon, Research Coordinator



DATE: February 15, 2017

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Psychology, Department of

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive
Intervention for Foster Preschoolers”

Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # 5, 6, 7

The amendment submitted on February 01, 2017 for the project identified above has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services using an expedited review procedure. This is a minimal risk study. This approval is based on the assumption that the materials, including changes/clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

The purpose of this Amendment is to:

- Add text message prompt;
- Add research staff, Da Yeon Kwon, Justyne Ortquist, and Kelsie Arsenault.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research according to the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
5. You will only use the approved informed consent document(s) (enclosed);
6. You will give each research subject a copy of the informed consent document;
7. If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the



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IRB approval expiration date. Without continuing approval the Protocol will automatically expire on November 22, 2017.

Additional Conditions: Any research personnel that have not completed CITI certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI certificates.

Approval period: February 15, 2017 - November 22, 2017

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Christina (Davis) Spicer, J.D., C.I.P.
Research Compliance Administrator
Research Compliance Services
University of Oregon



DATE: April 13, 2017

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # 5, 6, 7**

The amendment submitted on March 28, 2017 for the project identified above has been reviewed and approved by the University of Oregon Institutional Review Board (IRB) and Research Compliance Services using an expedited review procedure. This is a minimal risk study. This approval assumes that the materials, including changes/ clarifications that you submitted to the IRB contain a complete and accurate description of all the ways in which human subjects are involved in your research.

For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a). The IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

The purpose of this Amendment is to:

- Add two new versions of the consent form for families that enter the study without enough time to complete all data collection points.
- Revise the Research Plan and recruitment materials accordingly.

This approval is given with the following standard conditions:

1. You are approved to conduct this research only during the period of approval cited below;
2. You will conduct the research in accordance with the plans and protocol submitted (approved copy enclosed);
3. You will immediately inform Research Compliance Services of any injuries or adverse research events involving subjects;
4. You will immediately request approval from the IRB of any proposed changes in your research, and you will not initiate any changes until they have been reviewed and approved by the IRB;
5. You will only use the approved informed consent document(s) (enclosed);
6. You will give each research subject a copy of the informed consent document;



7. **If your research is anticipated to continue beyond the IRB approval dates, you must submit a Continuing Review Request to the IRB approximately 60 days prior to the IRB approval expiration date. Without continuing approval, the Protocol will automatically expire on November 22, 2017.**

***Additional Conditions:** Any research personnel that have not completed CITI certificates should be removed from the project until they have completed the training. When they have completed the training, you must submit a Protocol Amendment Application Form to add their names to the protocol, along with a copy of their CITI certificates.*

Approval period: April 13, 2017 - November 22, 2017

The University of Oregon and Research Compliance Services appreciate your efforts to conduct research in compliance with University of Oregon Policy and federal regulations that have been established to ensure the protection of human subjects in research. Thank you for your cooperation with the IRB process.

Sincerely,

Daniel Berman
Research Compliance Administrator

CC: Kristen Greenley, Alex Wagnon



DATE: September 14, 2017

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # [5, 6, 7]**

The amendment submitted on September 13, 2017 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Add research personnel Tim Matthews, Huna Yim Dockery, Sarah Horn, Rod Salgado, Christina Gamache Martin, and Maureen Zalewski. Remove Hoda Tirafkan, Jillian Tusso, and Julia Bartlett.

This research has been determined to be no greater than minimal risk and qualifies for expedited review procedures. For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a) as the IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

Approval period: September 14, 2017 - November 22, 2017

If you anticipate the research will continue beyond the IRB approval period, you must submit a request for continuing review approximately 60 days prior to the expiration date. **Without continued approval, the protocol will expire on November 22, 2017 and human subject research activities must cease.** A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of



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this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.

The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Chris Duy
Research Compliance Specialist
Research Compliance Services

CC: Kristen Greenley
Alex Wagnon



DATE: November 20, 2017

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers"

**Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # [5, 6, 7]**

The amendment submitted on November 16, 2017 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Added: Traci Crum, Jack Kapustka, Rachel Klein, Ashlee Erickson; Removed: Maeghan Scriven, Nasina Ellis, Sarah Nachbar

This research has been determined to be no greater than minimal risk and qualifies for expedited review procedures. For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- • The permission of one parent or guardian is sufficient for a child's involvement in the research.
- • The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a) as the IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

Approval period: November 20, 2017 - October 31, 2018

If you anticipate the research will continue beyond the IRB approval period, you must submit a request for continuing review approximately 60 days prior to the expiration date.

Without continued approval, the protocol will expire on October 31, 2018 and human subject research activities must cease. A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.



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The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Chris Duy
Research Compliance Specialist
Research Compliance Services

CC: Kristen Greenley, Alex Wagnon

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS • RESEARCH COMPLIANCE SERVICES

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DATE: May 14, 2018

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers"

Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # 5, 6, 7

The amendment submitted on April 23, 2018 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Updating the protocol for assessment follow-up with a select group of families who have finished the study.
- Remove Matthews, Tim ; Yim Dockery, Huna ; Horn, Sarah ; Salgado, Rod; Ellis, Nasina; Nachbar, Sarah; Scriven, Maeghan; Skolnick, Kayleigh; Gamache Martin, Christina; Zalewski, Maureen from the research team.

This research has been determined to be no greater than minimal risk and qualifies for expedited review procedures. For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a) as the IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

Approval period: May 14, 2018 - October 31, 2018

If you anticipate the research will continue beyond the IRB approval period, you must submit a request for continuing review approximately 60 days prior to the expiration date. **Without continued approval, the protocol will expire on October 31, 2018 and human subject research activities must cease.** A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.



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The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Chris Duy
Research Compliance Administrator
Research Compliance Services

CC: Kristen Greenley, Alex Wagnon

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS • RESEARCH COMPLIANCE SERVICES

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DATE: July 24, 2018

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of IRB Review and Approval-Amendment
Expedited Review as per Title 45 CFR Part 46 # 5, 6, 7**

The amendment submitted on July 20, 2018 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Add Sylvia Shaykis to the research team;
- Remove Kristen Greenley, Celeste Mena, Jessie Moyer, Kelsie Arsenault, Traci Crum, Jack Kapustka, Rachel Klein, and Ashlee Erickson

This research has been determined to be no greater than minimal risk and qualifies for expedited review procedures. For this research, the following additional determinations have been made:

- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has waived the requirement to obtain child assent under 45 CFR 46.408(a) as the IRB determined that the capability of some or all of the children is so limited that they cannot reasonably be consulted, however, the altered assent process described in the protocol is to be utilized.

Approval period: July 24, 2018 - October 31, 2018

If you anticipate the research will continue beyond the IRB approval period, you must submit a request for continuing review approximately 60 days prior to the expiration date. **Without continued approval, the protocol will expire on October 31, 2018 and human subject research activities must cease.** A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.



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The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Chris Duy
Research Compliance Administrator
Research Compliance Services

CC: Alex Wagnon

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS • RESEARCH COMPLIANCE SERVICES

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DATE: February 05, 2019

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of CAS Psychology

RE: Protocol entitled, “(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers”

**Notice of Expedited IRB Review and Expedited Approval
Amendment Review**

The amendment submitted on January 28, 2019 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Add Andrea Imhof, Adriana Conn, Andi Casteel, Jinzhu Hong, Eric Nguy, Lauren Kinnucan, Madisen Wolleck, Michiko Srinutthakul, Millie Halverson, Rachel Rozenfeld, Rebecca Namyet, Rylee Siebers, Yubin Cho, and Gracie Arnone to the research team.
- Remove Mary Wood, Katherine Denney, and Melanie Berry

For this research, the following determinations have been made:

- This study has been reviewed under the pre-2018 Common Rule. The study has been determined to be no greater than minimal risk and to qualify for expedited review as per Title 45 CFR 46.110 under Categories 5, 6, & 7.
 - **Continuing Review is required for this study.**
- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child’s involvement in the research.
- The IRB has approved an altered informed consent procedure under 45 CFR 46.116(d) to allow for the follow-up verbal consent process as an extension of the consent procedure for the follow-up activities.

Approval period: February 05, 2019 - October 07, 2019

If you anticipate the research will continue beyond the IRB approval period, you must submit a **Continuing Review Application** at least 45-days prior to the expiration date. **Without continued approval, the protocol will expire on October 07, 2019 and human subject research activities must cease.** A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of



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this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.

The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Chris Duy
Research Compliance Administrator
Research Compliance Services

CC: Alex Wagnon



DATE: May 23, 2019

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
CAS Psychology - Psychology, Dept. of

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive
Intervention for Foster Preschoolers"

Notice of Expedited IRB Review and Expedited Approval
Amendment Review

The amendment submitted on May 22, 2019 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Add research staff: Bianca Benitez, Leticia Hayes, Sarah Horn, Leslie Roos, Elizabeth (Lizzie) Wilson

For this research, the following determinations have been made:

- This study has been reviewed under the pre-2018 Common Rule. The study has been determined to be no greater than minimal risk and to qualify for expedited review as per Title 45 CFR 46.110 under Category (5, 6, 7).
 - Continuing Review is required for this study.
- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has approved an altered informed consent procedure under 45 CFR 46.116(d) to allow for the follow-up verbal consent process as an extension of the consent procedure for the follow-up activities.

Approval period: May 23, 2019 - October 07, 2019

If you anticipate the research will continue beyond the IRB approval period, you must submit a Continuing Review Application at least 45-days prior to the expiration date. Without continued approval, the protocol will expire on October 07, 2019 and human subject research activities must cease. A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.



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The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Christina Spicer, J.D., C.I.P.



DATE: August 8, 2019

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
CAS Psychology - Psychology, Dept. of

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive
Intervention for Foster Preschoolers"

**Notice of Expedited IRB Review and Expedited Approval
Amendment Review**

The amendment submitted on August 05, 2019 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Addition of the following research personnel: Oscar Becerra, Melissa Casas Carreno, Fabiola Cruz Aguilar, Amina Curto Serrano, Mirna Espinoza, Ana Hernandez, Olivia Kim, Jacqueline Luna, Alejandro Valdez-Alvarez, Lucy Zepeda

For this research, the following determinations have been made:

- This study has been reviewed under the pre-2018 Common Rule. The study has been determined to be no greater than minimal risk and to qualify for expedited review as per Title 45 CFR 46.110 under Category (5, 6, 7).
 - Continuing Review is required for this study.
- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has approved an altered informed consent procedure under 45 CFR 46.116(d) to allow for the follow-up verbal consent process as an extension of the consent procedure for the follow-up activities.

Approval period: August 8, 2019 - October 07, 2019

If you anticipate the research will continue beyond the IRB approval period, you must submit a **Continuing Review Application** at least 45-days prior to the expiration date. **Without continued approval, the protocol will expire on October 07, 2019 and human subject research activities must cease.** A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.



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The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Carolyn J. Craig, PhD, CIP
Senior Research Compliance Administrator

CC: Alex Wagnon

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS • RESEARCH COMPLIANCE SERVICES

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DATE: November 18, 2019

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
CAS Psychology - Psychology, Dept. of

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers"

**Notice of Expedited IRB Review and Expedited Approval
Amendment Review**

The amendment submitted on November 14, 2019 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Add Research Staff: Bianca Benitez, Camille Poritzky; Removed: Gracie Arnone, Patricia Chamberlain, Hyoun Kim, Katherine Pears, Sylvia Shaykis, Sally Guyer, Oscar Becerra, Andi Casteel, Mirna Espinoza, Mille Halverson, Leticia Hayes, Jinzhu (Chloe) Hong, Olivia Kim, Lauren Kinnucan, Rebecca Namyet, Eric Nguy, Rachel Rozenfeld, Alejandro Valdez-Alvarez, Elizabeth (Lizzie) Wilson, Madison Wolleck, Luzzy Zepeda

For this research, the following determinations have been made:

- **This study has been reviewed under the pre-2018 Common Rule. The study has been determined to be no greater than minimal risk and to qualify for expedited review as per Title 45 CFR 46.110 under Category (5, 6, 7).**
 - **Continuing Review is required for this study.**
- **The activities approved with this continuation are limited to data analysis only.** No new enrollment, consenting, or data collection may occur under this approval status; any previously approved consents may not be used. If you would like to reopen enrollment or collect new data for this protocol please submit an amendment application.
- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has approved an altered informed consent procedure under 45 CFR 46.116(d) to allow for the follow-up verbal consent process as an extension of the consent procedure for the follow-up activities.

Approval period: November 18, 2019 - October 14, 2020

If you anticipate the research will continue beyond the IRB approval period, you must submit a **Continuing Review Application** at least 45-days prior to the expiration date. **Without continued approval, the protocol will expire on October 14, 2020 and human subject research activities must cease.** A closure report must be submitted once human subject



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research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.

You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.

The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Christina Spicer, J.D., C.I.P.

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS ● RESEARCH COMPLIANCE SERVICES

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DATE: March 11, 2020

IRB Protocol Number: 06112013.016

TO: Philip Fisher, Principal Investigator
Department of Psychology

RE: Protocol entitled, "(KEEP-P) Randomized Trial of KEEP-P, a Preventive Intervention for Foster Preschoolers"

Notice of Expedited IRB Review and Expedited Approval Amendment Review

The amendment submitted on March 10, 2020 for the project identified above has been reviewed and approved by the Committee for Protection of Human Subjects (CPHS), the University of Oregon Institutional Review Board (IRB). The IRB has approved the changes to the research as described in the attached materials. As a reminder, it is your responsibility to submit any proposed changes for IRB review and approval prior to implementation.

Amendment Description:

- Addition of Camy Sibley to research personnel.

For this research, the following determinations have been made:

- This study has been reviewed under the **pre-2018 Common Rule**. The study has been determined to be no greater than minimal risk and to qualify for expedited review as per Title 45 CFR 46.110 under Categories 5, 6, & 7.
 - Continuing Review is required for this study.
- **The activities approved with this continuation are limited to data analysis only.** No new enrollment, consenting, or data collection may occur under this approval status; any previously approved consents may not be used. If you would like to reopen enrollment or collect new data for this protocol please submit an amendment application.
- The study as described satisfies the requirements for additional protections for children involved as subjects in research under 45 CFR Part 46.404.
- The permission of one parent or guardian is sufficient for a child's involvement in the research.
- The IRB has approved an altered informed consent procedure under 45 CFR 46.116(d) to allow for the follow-up verbal consent process as an extension of the consent procedure for the follow-up activities.

Approval period: March 11, 2020 - October 14, 2020

If you anticipate the research will continue beyond the IRB approval period, you must submit a **Continuing Review Application** at least 45-days prior to the expiration date. **Without continued approval, the protocol will expire on October 14, 2020 and human subject research activities must cease.** A closure report must be submitted once human subject research activities are complete. Failure to maintain current approval or properly close the protocol constitutes non-compliance.



You are responsible for adhering to the *Investigator Agreement* submitted with the initial application for IRB review. The responsibilities of the agreement are reiterated at the end of this letter below. You are responsible for conduct of the research and must maintain oversight of all research personnel to ensure compliance with the IRB approved protocol.

The University of Oregon and Research Compliance Services appreciate your commitment to the ethical and responsible conduct of research with human subjects.

Sincerely,

Brandi Fleck
Research Compliance Administrator

INVESTIGATOR AGREEMENT

Principal Investigator and Faculty Advisor Responsibilities

A. Conduct of the Research

1. I accept responsibility for the ethical conduct of this research and protection of participants as set forth in the [Belmont Report](#), [Declaration of Helsinki](#), the [Nuremberg Code](#), the [Common Rule](#), and the ethical principles of my discipline.
2. I accept responsibility for the conduct of this research ensuring this research is conducted according to
 - a. sound research design and methods;
 - b. the IRB approved protocol including the informed consent process;
 - c. the applicable terms of the grant, contract and/or signed funding agreements; and
 - d. applicable laws and regulations, including those for protecting the rights, safety, and welfare of human subjects.
3. I certify that I am or my faculty advisor is sufficiently qualified by education, training, and/or experience to assume responsibility for the proper conduct of this research. I accept responsibility for ensuring that members of this research team, including study staff and trainees, are appropriately qualified, trained and supervised.
4. I accept responsibility to personally conduct and/or directly supervise this research. I certify that I have sufficient time and resources to properly conduct and/or supervise this research for which I am responsible.

B. Ensuring and Maintaining Compliance

1. I will comply with relevant regulatory and institutional requirements, including those relating to conflicts of interest, responsible conduct of research and research misconduct.



INVESTIGATOR AGREEMENT

Principal Investigator and Faculty Advisor Responsibilities

2. I understand it is my responsibility to ensure that any research personnel, including myself, responsible for the design, conduct, and reporting of research declare any potential conflicts of interests related to the research and to maintain current records. I will ensure changes in conflicts of interest are promptly disclosed to the IRB.
3. I will ensure that informed consent is obtained as approved by the IRB and a copy is provided to participants, unless the IRB waives these requirements.
4. I will obtain initial IRB approval prior to implementing human subject research activities as well as prior approval for any amendments to this research.
5. I will conduct this research within the approval period issued by the IRB. I agree to submit a request for continuing review of this research at least 45 days in advance of the expiration date.
6. I will submit a closure report form prior to protocol expiration or within 45 days of completion of all activities involving human subjects or identifiable participant data.
7. I will maintain approval, as applicable, with collaborative entities including approvals from other countries or jurisdictions.
8. I will promptly report to the IRB (no later than seven days of discovery) any instances of noncompliance with the approved protocol or requirements of the IRB and any unanticipated problems.
9. I will assist in the facilitation of any monitoring and/or auditing of study activities and/or records as required by the IRB, funding entities, sponsors, and any federal and state regulatory agencies.

C. Investigator Records, Reports and Documentation

1. I will maintain research records, all protocol materials, and any other documents associated with this research (e.g., research plan, signed consent forms, and IRB correspondence).
2. I will maintain records for at least three years after this research ends, or for the length of time specified in applicable regulations or institutional or sponsor requirements, whichever is longer. I will take measures to prevent accidental or premature destruction of these documents.
3. I will ensure the safe and secure storage of this research data (whether in paper or electronic formats) and for protecting the confidentiality of the data in accordance with the approved protocol.
4. I will submit written reports to the IRB and permit inspection of the research records as required by the IRB.

Statement of Informed Consent: Caseworker

KEEP-P project

The foster family of a child on your caseload has been invited to be in a research project at the University of Oregon Prevention Science Institute called Keeping Foster and Kinship Parents Supported and Trained – Preschoolers (KEEP-P); the child will participate in parent-child interactions and developmental assessments. The KEEP-P project's main goal is to find out what type of services can be helpful for foster families, particularly in reducing stress for foster parents and young foster children and in improving placement stability. This study is being conducted by Phil Fisher, PhD from the University of Oregon. Dr. Fisher is also affiliated with Oregon Social Learning Center (OSLC) and OSLC Community Programs. The National Institute of Child Health and Human Development is funding this project (grant #1R01HD0757516-01).

Do you want this child to participate?

As this child's caseworker, you are part of the decision process for this child to be in the project. The child's foster parent(s) will also provide consent. Before you decide, you need to know the risks and benefits for this child. You should also know what we would ask him/her to do. Please take your time to read this form. The form explains the project. A staff member will also explain the project and answer your questions.

If you allow this child to be in this project, you will sign this consent form. When you sign the consent form, you "give consent." This means that you agree to allow this child to be in the project. It also means that you understand what we will ask him/her to do. Please review this form and the consent form carefully. Staff will answer any questions you have before you sign this form.

What is the purpose of the project?

KEEP-P is a new program being evaluated by researchers at the University of Oregon (UO). This project is a research and intervention study. We collect information about foster parents and children's lives. We will use this information to learn more about caregiver stress and child behavior. During this study, the child will complete one pre-test visit and one post-test visits. This project will compare two types of parenting support. What makes this a research study is that we don't know which is better. By the end of the project, we hope to know more about the types of support that best help parents.

Every child in the project will be put into one of two groups. Both groups will attend parent meetings for 12 weeks. All families will do the research assessments described below. One group will do the regular KEEP-P curriculum and one group will do a revised version (KEEP-V) that includes a video coaching component. The family/child will be put in one of these groups randomly, such as by a lottery system. You will not be able to choose the group. This is part of the research design.

KEEP-P parent groups have two main purposes: (1) to help parents build skills to support their child's development and (2) to provide parents with support. Topics include tools caregivers can use everyday like setting up routines, praising good behavior and setting limits. KEEP-P foster parent groups meet weekly for twelve-weeks. Groups are two hours long. Childcare and food is provided.

KEEP-V includes video coaching. The KEEP-V facilitator will film the caregiver and child together and show the caregiver clips of the things that they are already doing to help the child learn and grow. The filming sessions are quick and easy. Every other week, a facilitator will meet with the caregiver and child at their home or at the group location to film them both together for 10 minutes doing everyday activities like playing or having a snack. The next week at the group meeting the facilitator will show parts of the video in which families are doing things that support

the child's development. The coach will encourage caregivers to notice these skills at home in-between sessions. Whether you, or the family and/or child, choose to take part in this research or not, none of the usual services the family or child receive through the child welfare system will be affected.

What will we ask the child to do if she/he joins the project?

We will ask the child to do two interviews over the next 18 months. The details of each visit are listed in the chart below:

Interviews		What will happen	How long	How much you will receive
“BASELINE”				
1 st	Foster Parent	In person interview & questionnaires Videotaped interaction between foster parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Foster Child	Game-like activities	About 90 mins.	Prize
		Parent Group Meetings	2 hours a week for 12 weeks	
“6 MONTH”				
2 nd	Foster Parent	In person interview & questionnaires Videotaped interaction between foster parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Foster Child	Game-like activities	About 90 mins.	Prize
“12 MONTH”				
3 rd	Foster Parent	Interview & questionnaires	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
“18 MONTH”				
4 th	Foster Parent	Interview & questionnaires	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	

The interviews and questionnaires cover many topics. We will be asking the foster parent about the child's behaviors, social skills, and about parenting practices and attitudes. We will ask the foster parent and the child to complete parent-child interaction games/tasks and will be completing developmental assessments with the child. We will also be calling the foster parent 3 times after each assessment period to ask about the child's behaviors. The parent groups occur between the 1st interview and the 2nd interview.

What other types of information will the project collect?

This project collects information in different ways. We will ask the child to interact with project staff during game-like activities. This child will also be asked to interact with his/her caregiver in an activity. We will also collect information from foster parents from questionnaires. We record activities with video cameras.

We also collect:

- information from agencies such as child welfare
- physical information (height, weight, head circumference)

How long is the project?

The project is planned to last for five years until June 2018. The child will be asked to be in 6 months of this project but we will collect data about the child for 18 months.

Who else will take part?

About 240 children and their foster parents will be in this project. All of the families have foster children who are ages 2.5 to 6 years old.

Would the UO ever ask this family to stop participating?

Yes, sometimes situations change. For example, this child might return home to his/her biological parents or move to another foster home. If the child leaves his/her current foster placement, the foster family would no longer be able to participate. We will continue to ask for the child's participation, seeking consent from the child's current caregiver (foster, biological, adoptive).

What happens if the child needs more or different services/treatment?

Sometimes you or project staff might feel that the child needs other help. We can give you or their current caregiver information or contacts for other services.

What are this child's rights as a participant in this project?

This child has certain rights while he/she is in this project. These rights help protect him/her.

- You and this child can decide to be in the project or not. It is voluntary and always your and the child's choice.
- You or this child can change your mind about being in this project at any time. If this child decides to quit the project, or if you decide that the child should quit the project, there will be no negative results of any kind.
- The child can choose not to participate in any or all of the interview activities. They are important to the project and we would like him/her to answer them completely. But if there are some questions he/she does not want to answer or activities he/she does not want to complete, he/she may skip them and move on to other questions.
- The child also has the right not to do other parts of the project.
- You will get a copy of this Consent Form.
- You and this child are free to ask questions about the project at any time. You may contact the Principal Investigator, Phillip Fisher, PhD at 541-346-4968 or philf@uoregon.edu or the Program Manager, Kristen Greenley at 541-346-8073 or kdg@uoregon.edu. You can call collect. The address is: 427 LISB 6217 University of Oregon, Eugene, OR 97403.
- If you would like to contact someone outside the study with questions or concerns about the study or your rights or the child's rights as a research participant, please feel free to contact the Research Compliance Services, 5237 University of Oregon, Eugene, OR 97403, (541) 346-2510. The UO Research Compliance Services oversees the review of the research to protect your rights and is not involved with this study.

How will this child's privacy (or confidentiality) be protected?

We will do all we can to keep everything about this child completely private. Here are the ways that we protect his/her privacy.

- We use a number instead of his/her name on all the information about him/her that we study and analyze.
- We store all information in safe, locked areas.
- We study information from everyone in the project as a group, not as individuals. When we share project results, we will not identify any one person. We will not use names or other personal information.
- We train all staff members to protect the child's privacy. Only a small number of them will see his/her information. In some cases, the agency, the *National Institutes of Child Health and Human Development*, that is responsible for and funding this project might see information about him/her as part of their review of our project. They are also required to protect this child's privacy.
- We will not share this child's answers with anyone without your permission. We will not share anyone else's answers with you or this child, including answers from his/her family members/caregivers.

Are there times when we will share information about this child?

Yes, these are called "exceptions to confidentiality." Project staff will keep all of this child's information private, except in the following cases:

- We might hear or see something that we think is current or past abuse of a child. We might see or hear something that tells us that a child is in danger. Or we might learn that a child has witnessed violence (such as adults fighting in the home). In cases like these, we will take action to protect the child. We will talk to the child's caregiver and/or the child welfare agency.
- We will also report if we hear that this child plans to hurt themselves or someone else.

What are the possible risks to this child as a participant in the project?

As a participant in this project, there are a few risks:

- We collect personal information about this child. There is the chance that someone who should not see his/her information might see it.
- This child might feel uncomfortable with some parts of the project. For example, the game-like activities may be frustrating to some children. He/she is free to say "no" or stop at any part.

What are the benefits to this family and child as participants?

Potential benefits for the children include prevention of behavioral and emotional problems and improved adjustment at home, in daycare, preschool and school, and in the community. Benefits to foster, kin, and biological parents may be an increase in their knowledge and ability to work with their child, resulting in greater satisfaction in their role as parents or foster parents. In addition, with increased skills, foster parents may be less likely to request that a foster child be removed because of difficult behaviors. All participants are expected to benefit in that they will derive satisfaction from contributing to the knowledge gained from this research.

What will be done with the information we collect for this project?

We will use information from this project for research and education only. We will share the results of the project in papers, books and presentations. We might share results and data with other education or research centers. We will not use names or other personal information when we share project results or data.

I have read and I understand the information on this consent form. I have had all my questions answered. I agree to participate in the KEEP-P research and intervention study at the University of Oregon, Prevention Science Institute.

Signature

Date

Print name

Participating Child's Name

KEEP-P Staff Signature

Authorization for Audiovisual Recording

I authorize the KEEP-P team to use audiovisual recording made of the child for the purpose of providing services and training.

Upon written notice I may have all of the audiovisual recordings erased and/or restrict their use to one or more of the above stated purposes. I understand that all audiovisual recordings are available for viewing by me.

Print name _____ Date _____ Initial _____

Statement of Informed Consent: Caregiver **KEEP-P project**

You are invited to be in a research project at the University of Oregon Prevention Science Institute called Keeping Parents Supported – Preschoolers (KEEP-P) with your foster child. The KEEP-P project's main goal is to find out what type of services can be helpful for foster families, particularly in reducing stress for foster parents and young foster children and in improving placement stability. This study is being conducted by Phil Fisher, PhD from the University of Oregon. Dr. Fisher is also affiliated with Oregon Social Learning Center (OSLC) and OSLC Community Programs. The National Institute of Child Health and Human Development is funding this project (grant #1R01HD0757516-01).

Do you want to participate?

It is your decision to be in the project and to give permission for your foster child to be in the project. Before you decide, you need to know the risks and benefits. You should also know what we will ask you and your child to do. Please take your time to read this form. The form explains the project. A staff member will also explain the project and answer your questions.

If you agree to be in this project you will sign this consent form. When you sign the consent form, you “give consent.” This means that you agree to be in the project. It also means that you understand what we will ask you to do. Please review this form and the consent form carefully. Staff will answer any questions you have before you sign these forms.

What is the purpose of the project?

KEEP-P is a new program being evaluated by researchers at the University of Oregon (UO). This project is a research and intervention study. We will collect information about foster parents and children's lives. We will use this information to learn more about caregiver stress, child placement stability, and child behavior. This project will compare two types of parenting support. What makes this a research study is that we don't know which is better. By the end of the project, we hope to know more about the types of support that best help parents.

Every family in the project will be put into one of two groups. Both groups will attend parent meetings for 12 weeks. One group will do the regular KEEP-P curriculum and one group will do a revised version (KEEP-V) that includes a video coaching component. You will be put in one of the groups randomly, such as by a lottery system. You will not be able to choose the group. This is part of the research design.

KEEP-P parent groups have two main purposes: (1) to help foster parents build skills to support their child's development and (2) to provide foster parents with support. Topics include tools foster parents can use everyday like setting up routines, praising good behavior and setting limits. KEEP-P parent groups meet weekly for twelve-weeks. Groups are two hours long. Childcare and food is provided.

KEEP-V includes video coaching. Your KEEP-V facilitator will film you and your child together and show you clips of things that you are already doing that help your child learn and grow. The filming sessions are quick and easy. Every other week, your facilitator will meet with you at home or at the group location to film you and your child together for 10 minutes doing everyday activities like playing or having a snack. The next week at the group meeting your facilitator will show parts of the video in which you are doing things that support your child's development. Your coach will encourage you to notice these skills at home in-between sessions.

Whether you choose to take part in this research or not, none of the usual services you receive through the child welfare system will be affected. However, because this is a research and intervention study participants who take part in the research will have priority in attending the parent group meetings.

What will we ask you to do if you choose to be in the project?

We will ask you and your foster child to do two interviews and then two more with just you, over the course of the next 18 months. The details of each visit are listed in the chart below:

Interviews		What will happen	How long	How much you will receive
“BASELINE”				
1 st	Foster Parent	In person interview & questionnaires Videotaped interaction between foster parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Foster Child	Game-like activities	About 90 mins.	Prize
		Parent Group meetings	2 hours a week for 12 weeks	
“6 MONTH”				
2 nd	Foster Parent	In person interview & questionnaires Videotaped interaction between foster parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Foster Child	Game-like activities	About 90 mins.	Prize
“12 MONTH”				
3 rd	Foster Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
“18 MONTH”				
4 th	Foster Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	

The interviews and questionnaires cover many topics. We will be asking you about your child’s behaviors, social skills, and about parenting practices and attitudes. We will ask you and your child to complete parent- child interaction games/tasks and will be completing developmental assessments with your child. We will also be calling you 3 times after each assessment period to ask about your child’s behaviors. The parent groups occur between the 1st interview and the 2nd interview.

What other types of information will the project collect?

This project collects information in different ways. We will ask your child to interact with project staff during game-like activities and we will ask your child to interact with you in an activity. We will ask you questions using questionnaires. You will answer questions on paper or on a computer. We record activities with video cameras.

We also collect:

- information from agencies such as child welfare
- physical information (height, weight, head circumference)

How long is the project?

The project is planned to last for five years until June 2018. You and your family will be asked to be in 18 months of this project.

Who else will take part?

About 240 children and their foster parents will be in this project. All of the families have foster children who are ages 2.5 to 6 years old.

Would the U of O ever ask you to stop participating?

Yes, sometimes situations change. For example, your foster child might return home to his/her biological parents or move to another foster home. If your foster child leaves your home, you would no longer be able to participate. We will continue to ask for the child's participation, seeking consent from the child's current caregiver (foster, biological, adoptive).

What happens if you need more or different services/treatment?

Sometimes you or project staff might feel that you or your foster child needs other help. We can give you information or contacts for other services.

What are your rights as a participant in this project?

You have certain rights while you are in this project. These rights help protect you.

- You and your child can decide to be in the project or not. It is voluntary and always your and your child's choice.
- You can change your mind about being in this project at any time. If you decide to quit the project, there will be no negative results of any kind.
- You can skip or not answer any question. Some questions might be personal or sensitive. They are important to the project and we would like you to answer them honestly. But if there are some questions you do not want to answer, you may skip them and move on to other questions.
- You also have the right not to do other parts of the project.
- You will get a copy of this Consent Form.
- You are free to ask questions about the project at any time. You may contact the Principal Investigator, Phillip Fisher, PhD at 541-346-4968 or philf@uoregon.edu or the Project Coordinator, Kristen Greenley at 541-346-8073 or kdg@uoregon.edu. You can call collect.
The address is: 427 LISB, 6217 University of Oregon, Eugene, OR 97403.
- If you would like to contact someone outside the study with questions or concerns about the study or your rights as a research participant, please feel free to contact the Research Compliance Services, 5237 University of Oregon, Eugene, OR 97403, (541) 346-2510. The UO Research Compliance Services oversees the review of the research to protect your rights and is not involved with this study.

How will your privacy (or confidentiality) be protected?

We will do all we can to keep everything about you and your family completely private. Here are the ways that we protect your privacy.

- We use a number instead of your name on all the information about you that we study and analyze.
- We store all information in safe, locked areas.
- We study information from everyone in the project as a group, not as individuals. When we share project results, we will not identify any one person. We will not use names or other personal information.
- We train all staff members to protect your privacy. Only a small number of them will see your information. In some cases, the agency, the *National Institute of Child Health and Human Development*, that is responsible for and funding this project might see information about you as part of their review of our project. They are also required to protect your privacy.
- We will not share your answers with anyone without your permission. We will not share anyone else's answers with you, including answers from your family members.

Are there times when we will share information about you?

Yes, these are called “exceptions to confidentiality.” Project staff will keep all of your information private, except in the following cases:

- We might hear or see something that we think is abuse of a child. We might see or hear something that tells us that a child is in danger. Or we might learn that a child has witnessed violence (such as adults fighting in the home). In cases like these, we will take action to protect the child. We will talk to you and/or the child welfare agency.
- We will also report when we hear that someone plans to hurt themselves or someone else.

What are the possible risks to you as a participant in the project?

As a participant in this project, there are a few risks to you:

- We collect personal information about you and your foster child. There is the chance that someone who should not see your information might see it.
- You might feel uncomfortable with some parts of the project. For example, some questions we ask are personal. Or you might feel uncomfortable being videotaped. You are free to say “no” to any part.

What are the benefits to you as a participant?

Potential benefits for the children include prevention of behavioral and emotional problems and improved adjustment at home, in daycare, preschool and school, and in the community. Benefits to foster, kin, and biological parents may be an increase in their knowledge and ability to work with their child, resulting in greater satisfaction in their role as parents or foster parents. In addition, with increased skills, foster parents may be less likely to request that a foster child be removed because of difficult behaviors. All participants are expected to benefit in that they will derive satisfaction from contributing to the knowledge gained from this research.

Payments

If you receive over \$600 per year from the University of Oregon for participating in research studies, you will be asked to fill out information for an IRS W9 form for tax purposes. We will report the amount you receive as a participant for tracking purposes.

What will be done with the information we collect for this project?

We will use information from this project for research and education only. We will share the results of the project in papers, books and presentations. We might share results and data with other education or research centers. We will not use names or other personal information when we share project results or data.

I have read and I understand the information on this consent form. I have had all my questions answered. I agree to take part in the KEEP-P research and intervention study at the University of Oregon, Prevention Science Institute.

Signature

Date

Print name

Signature

Date

Print name

Print Participating Child's Name

Staff Signature

Date

Authorization for Audiovisual Recording

I authorize the KEEP-P team to use audiovisual recording made of me (us) and of my (our) family for the purpose of providing services and training.

Upon written notice I (we) may have all of the audiovisual recordings erased and/or restrict their use to one or more of the above stated purposes. I (we) understand that all audiovisual recordings are available for viewing by me (us). This release must be initialed by all family members 14 years or over participating in services.

Print name _____ Date _____ Initial _____

Print name _____ Date _____ Initial _____

Statement of Informed Consent: Parent
KEEP-P project

You are invited to be in a continuing research project at the University of Oregon Prevention Science Institute called, Keeping Parents Supported – Preschoolers (KEEP-P) with your child. The KEEP-P project's main goal is to find out what type of services can be helpful for foster parents, particularly in reducing stress and improving placement stability. This study is being conducted by Phil Fisher, PhD from the University of Oregon. Dr. Fisher is also affiliated with Oregon Social Learning Center (OSLC) and OSLC Community Programs. The National Institute of Child Health and Human Development is funding this project (grant #1R01HD0757516-01).

Do you want to participate?

It is your decision to be in the project and to give permission for your child to be in the project. Before you decide, you need to know the risks and benefits. You should also know what we will ask you and your child to do. Please take your time to read this form. The form explains the project. A staff member will also explain the project and answer your questions.

If you agree to be in this project you will sign this consent form. When you sign the consent form, you “give consent.” This means that you agree to be in the project. It also means that you understand what we will ask you to do. Please review this consent form carefully. Staff will answer any questions you have before you sign the form.

What is the purpose of the project?

KEEP-P is a new program being evaluated by researchers at the University of Oregon (UO). This project is a research and intervention study. We collect information about parents and children's lives. We will use this information to learn more about caregiver stress, child placement stability, and child behavior. By the end of the project, we hope to know more about the types of support that best help children.

Whether you choose to take part in this research or not, none of the usual services you may receive through the child welfare system will be affected.

What will we ask you to do if you choose to be in the project?

This chart lists the details of the visit(s):

NOTE: the caregiver/parent will receive the version of the chart that coincides with the Interview time point.

[VERSION FOR PARENTS JOINING STUDY AT 6 MONTH VISIT]

Interviews		What will happen	How long	How much you will receive
“6 MONTH”				
1st	Caregiver/Parent	In person interview & questionnaires Videotaped interaction between parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Child	Game-like activities	About 90 mins.	Prize
“12 MONTH”				
2nd	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
“18 MONTH”				
3rd	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	

[VERSION FOR PARENTS JOINING STUDY AT 12 MONTH VISIT]

Interviews		What will happen	How long	How much you will receive
“12 MONTH”				
1st	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
“18 MONTH”				
2nd	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	

[VERSION FOR PARENTS JOINING STUDY AT 18 MONTH VISIT]

Interviews		What will happen	How long	How much you will receive
"18 MONTH"				
	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	

The interviews and questionnaires cover many topics. We will be asking you about your child's behaviors, social skills, and about parenting practices and attitudes. **[For 6 MONTH interview only]** We will ask you and your child to complete parent-child interaction games/tasks and will be completing developmental assessments with your child. We will also be calling you 3 times after each assessment period to ask about your child's behaviors.

What other types of information will the project collect?

This project collects information in different ways. **[For 6 MONTH interview only]** We will ask your child to interact with project staff during game-like activities and we will ask your child to interact with you in an activity. We will ask you questions using questionnaires. You will answer questions on paper or on a computer. **[For 6 MONTH interview only]** We record activities with video cameras.

We also collect:

- information from agencies such as child welfare
- physical information (height, weight, head circumference) **[For 6 MONTH interview only]**

How long is the project?

The project is planned to last for five years until June 2018. You and your family will be asked to be in **[12, 6 or 1 month(s)]** of this project.

Who else will take part?

About 240 children and their caregivers will be in this project.

Would the U of O ever ask you to stop participating?

Yes, sometimes situations change. If your child leaves your home, you would no longer be able to participate. If this happens, we may continue to ask for the child's participation, seeking consent from the child's current caregiver.

What happens if you need more or different services/treatment?

Sometimes you or project staff might feel that you or your child needs help. We can give you information or contacts for other services.

What are your rights as a participant in this project?

You have certain rights while you are in this project. These rights help protect you.

- You and your child can decide to be in the project or not. It is voluntary and always your and your child's choice.
- You can change your mind about being in this project at any time. If you decide to quit the project, there will be no negative results of any kind.
- You can skip or not answer any question. Some questions might be personal or sensitive. They are important to the project and we would like you to answer them honestly. But if there are some questions you do not want to answer, you may skip them and move on to other questions.
- You also have the right not to do other parts of the project.
- You will get a copy of this Consent Form.
- You are free to ask questions about the project at any time. You may contact the Principal Investigator, Phillip Fisher, PhD at 541-346-4968 or philf@uoregon.edu or the Project Coordinator,

Kristen Greenley at 541-346-8073 or kdg@uoregon.edu. You can call collect.
The address is: 427 LISB, 6217 University of Oregon, Eugene, OR 97403.

- If you would like to contact someone outside the study with questions or concerns about the study or your rights as a research participant, please feel free to contact the Research Compliance Services, 5237 University of Oregon, Eugene, OR 97403, (541) 346-2510. The UO Research Compliance Services oversees the review of the research to protect your rights and is not involved with this study.

How will your privacy (or confidentiality) be protected?

We will do all we can to keep everything about you and your family completely private. Here are the ways that we protect your privacy.

- We use a number instead of your name on all the information about you that we study and analyze.
- We store all information in safe, locked areas.
- We study information from everyone in the project as a group, not as individuals. When we share project results, we will not identify any one person. We will not use names or other personal information.
- We train all staff members to protect your privacy. Only a small number of them will see your information. In some cases, the agency, the *National Institute of Child Health and Human Development*, that is responsible for and funding this project might see information about you as part of their review of our project. They are also required to protect your privacy.
- We will not share your answers with anyone without your permission. We will not share anyone else's answers with you, including answers from your family members.

Are there times when we will share information about you?

Yes, these are called "exceptions to confidentiality." Project staff will keep all of your information private, except in the following cases:

- We might hear or see something that we think is abuse of a child. We might see or hear something that tells us that a child is in danger. Or we might learn that a child has witnessed violence (such as adults fighting in the home). In cases like these, we will take action to protect the child. We will talk to you and/or the child welfare agency.
- We will also report when we hear that someone plans to hurt themselves or someone else.

What are the possible risks to you as a participant in the project?

As a participant in this project, there are a few risks to you:

- We collect personal information about you and your child. There is the chance that someone who should not see your information might see it.
- You might feel uncomfortable with some parts of the project. For example, some questions we ask are personal. Or you might feel uncomfortable being videotaped. You are free to say "no" to any part.

What are the benefits to you as a participant?

Potential benefits for the children include prevention of behavioral and emotional problems and improved adjustment at home, in daycare, preschool and school, and in the community. Benefits to foster, kin, and biological parents may be an increase in their knowledge and ability to work with their child, resulting in greater satisfaction in their role as parents or foster parents. All participants are expected to benefit in that they will derive satisfaction from contributing to the knowledge gained from this research.

Payments

If you receive over \$600 per year from the University of Oregon for participating in research studies, you will be asked to fill out information for an IRS W9 form for tax purposes. We will report the amount you receive as a participant for tracking purposes.

What will be done with the information we collect for this project?

We will use information from this project for research and education only. We will share the results of the project in papers, books and presentations. We might share results and data with other education or research centers. We will not use names or other personal information when we share project results or data.

I have read and I understand the information on this consent form. I have had all my questions answered.

I give permission for my own participation and **[For 6 MONTH interview only]** my child (listed below) to take part in the KEEP-P research study at the University of Oregon, Prevention Science Institute.

[For 6 MONTH interview only] By signing this consent, I am stating that I am legally authorized to consent for this child to take part.

Signature

Date

Print name

Signature

Date

Print name

Print Participating Child's Name

Staff Signature

Date

[For 6 MONTH interview only] Authorization for Audiovisual Recording

I authorize the KEEP-P team to use audiovisual recording made of me (us) and of my (our) family for the purpose of providing services and training.

Upon written notice I (we) may have all of the audiovisual recordings erased and/or restrict their use to one or more of the above stated purposes. I (we) understand that all audiovisual recordings are available for viewing by me (us). This release must be initialed by all family members 14 years or over participating in services.

Print name _____ Date _____ Initial _____

Print name _____ Date _____ Initial _____

Statement of Informed Consent: Parent
KEEP-P project

You are invited to be in a continuing research project at the University of Oregon Prevention Science Institute called, Keeping Parents Supported – Preschoolers (KEEP-P) with your child. The KEEP-P project’s main goal is to find out what type of services can be helpful for parents, particularly in reducing stress and improving placement stability. This study is being conducted by Phil Fisher, PhD from the University of Oregon. Dr. Fisher is also affiliated with Oregon Social Learning Center (OSLC) and OSLC Community Programs. The National Institute of Child Health and Human Development is funding this project (grant #1R01HD0757516-01).

Do you want to participate?

It is your decision to be in the project and to give permission for your child to be in the project. Before you decide, you need to know the risks and benefits. You should also know what we will ask you and your child to do. Please take your time to read this form. The form explains the project. A staff member will also explain the project and answer your questions.

If you agree to be in this project you will sign this consent form. When you sign the consent form, you “give consent.” This means that you agree to be in the project. It also means that you understand what we will ask you to do. Please review this consent form carefully. Staff will answer any questions you have before you sign the form.

What is the purpose of the project?

KEEP-P is a new program being evaluated by researchers at the University of Oregon (UO). This project is a research and intervention study. We will collect information about parents and children’s lives. We will use this information to learn more about caregiver stress, and child behavior. By the end of the project, we hope to know more about the types of support that best help children.

Every family in the project will be put into one of two groups. Both groups will attend parent meetings for 12 weeks. One group will do the regular KEEP-P curriculum and one group will do a revised version (KEEP-V) that includes a video coaching component. You will be put in one of the groups randomly, such as by a lottery system. You will not be able to choose the group. This is part of the research design.

KEEP-P parent groups have two main purposes: (1) to help parents build skills to support their child’s development and (2) to provide parents with support. Topics include tools parents can use everyday like setting up routines, praising good behavior and setting limits. KEEP-P parent groups meet weekly for twelve-weeks. Groups are two hours long. Childcare and food is provided.

KEEP-V includes video coaching. Your KEEP-V facilitator will film you and your child together and show you clips of things that you are already doing that help your child learn and grow. The filming sessions are quick and easy. Every other week, your facilitator will meet with you at home or at the group location to film you and your child together for 10 minutes doing everyday activities like playing or having a snack. The next week at the group meeting your facilitator will show parts of the video in which you are doing things that support your child’s development. Your coach will encourage you to notice these skills at home in-between sessions.

Whether you choose to take part in this research or not, none of the other services your family receives (such as through EC CARES) will be affected. However, because this is a research and intervention study participants who take part in the research will have priority in attending the parent group meetings.

What will we ask you to do if you choose to be in the project?

We will ask you and your child to do two interviews and then two more with just you, over the course of the next 18 months.

This chart lists the details of the visit(s):

Interviews		What will happen	How long	How much you will receive
“BASELINE”				
1 st	Parent	In person interview & questionnaires Videotaped interaction between parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Child	Game-like activities	About 90 mins.	Prize
		Parent Group meetings	2 hours a week for 12 weeks	
“6 MONTH”				
2 nd	Parent	In person interview & questionnaires Videotaped interaction between parent and child	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
	Child	Game-like activities	About 90 mins.	Prize
“12 MONTH”				
3 rd	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	
“18 MONTH”				
4 th	Parent	Interview & questionnaires (Completed in person or by phone and mail)	About 90 mins.	\$50
		3 telephone interviews	5 minutes each	

The interviews and questionnaires cover many topics. We will be asking you about your child’s behaviors, social skills, and about parenting practices and attitudes. We will ask you and your child to complete parent-child interaction games/tasks and will be completing developmental assessments with your child. We will also be calling you 3 times after each assessment period to ask about your child’s behaviors.

The parent groups occur between the 1st interview and the 2nd interview.

What other types of information will the project collect?

This project collects information in different ways. We will ask your child to interact with project staff during game-like activities and we will ask your child to interact with you in an activity. We will ask you questions using questionnaires. You will answer questions on paper or on a computer. We record activities with video cameras.

We also collect physical information (height, weight, head circumference)

How long is the project?

The project is planned to last for five years until June 2018. You and your family will be asked to be in 18 months of this project.

Who else will take part?

About 240 children and their caregivers will be in this project.

What happens if you need more or different services/treatment?

Sometimes you or project staff might feel that you or your child needs help. We can give you information or contacts for other services.

What are your rights as a participant in this project?

You have certain rights while you are in this project. These rights help protect you.

- You and your child can decide to be in the project or not. It is voluntary and always your and your child's choice.
- You can change your mind about being in this project at any time. If you decide to quit the project, there will be no negative results of any kind.
- You can skip or not answer any question. Some questions might be personal or sensitive. They are important to the project and we would like you to answer them honestly. But if there are some questions you do not want to answer, you may skip them and move on to other questions.
- You also have the right not to do other parts of the project.
- You will get a copy of this Consent Form.
- You are free to ask questions about the project at any time. You may contact the Principal Investigator, Phillip Fisher, PhD at 541-346-4968 or philf@uoregon.edu or the Project Coordinator, Kristen Greenley at 541-346-8073 or kdg@uoregon.edu. You can call collect.
The address is: 427 LISB, 6217 University of Oregon, Eugene, OR 97403.
- If you would like to contact someone outside the study with questions or concerns about the study or your rights as a research participant, please feel free to contact the Research Compliance Services, 5237 University of Oregon, Eugene, OR 97403, (541) 346-2510. The UO Research Compliance Services oversees the review of the research to protect your rights and is not involved with this study.

How will your privacy (or confidentiality) be protected?

We will do all we can to keep everything about you and your family completely private. Here are the ways that we protect your privacy.

- We use a number instead of your name on all the information about you that we study and analyze.
- We store all information in safe, locked areas.
- We study information from everyone in the project as a group, not as individuals. When we share project results, we will not identify any one person. We will not use names or other personal information.
- We train all staff members to protect your privacy. Only a small number of them will see your information. In some cases, the agency, the *National Institute of Child Health and Human Development*, that is responsible for and funding this project might see information about you as part of their review of our project. They are also required to protect your privacy.
- We will not share your answers with anyone without your permission. We will not share anyone else's answers with you, including answers from your family members.

Are there times when we will share information about you?

Yes, these are called “exceptions to confidentiality.” Project staff will keep all of your information private, except in the following cases:

- We might hear or see something that we think is abuse of a child. We might see or hear something that tells us that a child is in danger. Or we might learn that a child has witnessed violence (such as adults fighting in the home). In cases like these, we will take action to protect the child. We will talk to you and/or the child welfare agency.
- We will also report when we hear that someone plans to hurt themselves or someone else.

What are the possible risks to you as a participant in the project?

As a participant in this project, there are a few risks to you:

- We collect personal information about you and your child. There is the chance that someone who should not see your information might see it.
- You might feel uncomfortable with some parts of the project. For example, some questions we ask are personal. Or you might feel uncomfortable being videotaped. You are free to say “no” to any part.

What are the benefits to you as a participant?

Potential benefits for the children include prevention of behavioral and emotional problems and improved adjustment at home, in daycare, preschool and school, and in the community. Benefits to biological parents may be an increase in their knowledge and ability to work with their child, resulting in greater satisfaction in their role as parents. All participants are expected to benefit in that they will derive satisfaction from contributing to the knowledge gained from this research.

Payments

If you receive over \$600 per year from the University of Oregon for participating in research studies, you will be asked to fill out information for an IRS W9 form for tax purposes. We will report the amount you receive as a participant for tracking purposes.

What will be done with the information we collect for this project?

We will use information from this project for research and education only. We will share the results of the project in papers, books and presentations. We might share results and data with other education or research centers. We will not use names or other personal information when we share project results or data.

I have read and I understand the information on this consent form. I have had all my questions answered.

I give permission for my own participation and my child (listed below) to take part in the KEEP-P research and intervention study at the University of Oregon, Prevention Science Institute.

By signing this consent, I am stating that I am legally authorized to consent for this child to take part.

Signature

Date

Print name

Signature

Date

Print name

Print Participating Child's Name

Staff Signature

Date

Authorization for Audiovisual Recording

I authorize the KEEP-P team to use audiovisual recording made of me (us) and of my (our) family for the purpose of providing services and training.

Upon written notice I (we) may have all of the audiovisual recordings erased and/or restrict their use to one or more of the above stated purposes. I (we) understand that all audiovisual recordings are available for viewing by me (us). This release must be initialed by all family members 14 years or over participating in services.

Print name _____ Date _____ Initial _____

Print name _____ Date _____ Initial _____



Keeping Parents Supported

Prevention Science Institute | 6217 University of Oregon | Eugene, OR 97403-6217 | (541) 346-4684

Date: _____

Consent for Mutual Exchange of Information

Child Name: _____ Birthdate: _____

Parent/Legal Guardian/Surrogate Parent Name: _____

This agency is hereby authorized to contact the following agencies or individuals listed below to share information which will help us to better serve you and your child. This authorization expires one year from the date signed. Choosing not to sign it will not affect your ability to participate.

Name

Type of Information

Parent Group
Progress

Other

(Specify)

Early Childhood CARES

University of Oregon, 299 E. 18th Ave. Eugene OR. 97401 (541)346-2578

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The parent has the right to revoke consent in writing at anytime.

Parent, guardian or surrogate parent signature

date

Parent, guardian or surrogate parent signature

date

Staff signature

date